change is due to new and unexpected findings in research on the drug, information arising from FDA recommendations, or unforeseen developments in treatment or diagnosis of the disease or condition.

(b) FDA will grant the amendment if it finds that the initial designation request was made in good faith and that the amendment is intended to conform the orphan-drug designation to the results of unanticipated research findings, to unforeseen developments in the treatment or diagnosis of the disease or condition, or to changes based on FDA recommendations, and that, as of the date of the submission of the amendment request, the amendment would not result in exceeding the prevalence or cost recovery thresholds in §316.21(a)(1) or (a)(2) upon which the drug was originally designated.

[78 FR 35134, June 12, 2013]

§ 316.27 Change in ownership of orphan-drug designation.

(a) A sponsor may transfer ownership of or any beneficial interest in the orphan-drug designation of a drug to a new sponsor. At the time of the transfer, the new and former owners are required to submit the following information to FDA:

(1) The former owner or assignor of rights shall submit a letter or other document that states that all or some rights to the orphan-drug designation of the drug have been transferred to the new owner or assignee and that a complete copy of the request for orphan-drug designation, including any amendments to the request, supplements to the granted request, and correspondence relevant to the orphan-drug designation, has been provided to the new owner or assignee.

(2) The new owner or assignee of rights shall submit a statement accepting orphan-drug designation and a letter or other document containing the following:

(i) The date that the change in ownership or assignment of rights is effective;

(ii) A statement that the new owner has a complete copy of the request for orphan-drug designation including any amendments to the request, supplements to the granted request, and correspondence relevant to the orphan-drug designation; and

(iii) A specific description of the rights that have been assigned and those that have been reserved. This may be satisfied by the submission of either a list of rights assigned and reserved or copies of all relevant agreements between assignors and assignees; and

(iv) The name and address of a new primary contact person or resident agent.

(b) No sponsor may relieve itself of responsibilities under the Orphan Drug Act or under this part by assigning rights to another person without:

(1) Assuring that the sponsor or the assignee will carry out such responsibilities; or

(2) Obtaining prior permission from FDA.

[57 FR 62085, Dec. 29, 1992; 58 FR 6167, Jan. 26, 1993]

§ 316.28 Publication of orphan-drug designations.

Each month FDA will update a publicly available cumulative posting of all drugs designated as orphan drugs. These postings will contain the following information:

(a) The name and address of the sponsor;

(b) The generic name and trade name, if any, or, if neither is available, the chemical name or a meaningful descriptive name of the drug;

(c) The date of the granting of orphan-drug designation;

(d) The designated use in the rare disease or condition; and

(e) If the drug loses designation after August 12, 2013, the date of it no longer having designation.

[78 FR 35134, June 12, 2013]

§ 316.29 Revocation of orphan-drug designation.

(a) FDA may revoke orphan-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this part; or